K011142

MAY - 8 2001

510(k) Premarket Notification Summary of Safety and Effectiveness Information	***Aquarius™ Workstation***

Device Name:
Trade Name: ***Aquarius™ Workstation***
Common Name: Image communication and storage system
Classification Name: System, Digital Image Communication Teleradiology System

Establishment Name & Registration Number:
Name: TeraRecon, Inc.
Number: Pending

Classification:
Title 21, Code of Federal Regulations, § 892.2020 & § 892.2050. Now proposed exempt, final rule pending.

ProCode: 90-LMD & 90-LLZ

Equivalent Device(s):
IiVS™ Integrated image Viewing Station (K994329).

Description of the Device:
The Aquarius Workstation is a device offered in various configurations, with the simplest configuration being a workstation capable of image review, communications, archiving, database maintenance, reporting and basic 3D capabilities. The fully configured workstation is also capable of full-color Volume Rendering, Calcium Scoring.

The intended use of the device is to provide solutions to various medical image viewing problems, which come about as modalities generate more and more images. It also supports image distribution over networks, and is DICOM conformant.

Applicant / Sponsor Name / Address:
TeraRecon, Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
650.372.2669

Contact Person:
Mr. Robert Taylor
Executive Vice President
TeraRecon, Inc.
2955 Campus Drive, Suite 325
San Mateo, CA 94403
650.372.2669

Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 / 925.356.2654 FAX

Manufacturing Facility:
At the present time, the ***Aquarius™ Workstation*** is manufactured by TeraRecon, Inc.

Performance Standards:
There are no applicable FDA mandated performance standards for this device. However, voluntary standards such as DICOM, various in-house Standard Operating Procedures and vendor qualification procedures are in place and utilized in the production of the software.

The software designed to control and manipulate the diagnostic images follows the international standard ISO/IEC 12207: 1995 Information Technology - Software Life Cycle Processes. In accordance with that standard, the level of concern relative to this software has been determined using the decision tree provided in Version 1 of the FDA Software Guidance.

Hardware requirements
The hardware platform for the Aquarius Workstation is an "off-the-shelf" personal computer running Microsoft Windows NT Version 4.0, or Microsoft Windows 2000, or equivalent. The workstation software supports single or multiple processors as supported by the operating system providing they are of the Pentium III class or equivalent. A minimum of 512MB memory is recommended, and a minimum of 18GB hard drive space. A standard Ethernet interface is recommended for network connectivity. A monitor appropriate for the intended use required.

User interface
The user interacts with the system through a standard keyboard and a wheel-mouse.

Data input:
DICOM transfer:
Compliance with DICOM 3.0 C-FIND
Compliance with DICOM 3.0 C-MOVE
Compliance with DICOM 3.0 C-STORE
Compliance with DICOM 3.0 C-PRINT
Import of DICOM files directly from supported media (e.g. Hard Drive or CD)
Maximum dataset size: 512 MB or 1000 slices

Data output:
Data output is user defined and supports one of the following formats:

DICOM file
JPEG image file
BMP file
Microsoft Word Document
Microsoft Excel Document
Microsoft Access Database
Modality supporting DICOM PRINT (optional)
Printer supported by Microsoft Windows (optional)
CD-R Media (optional)
MOD Media (optional)

The Report Function
Provide preset image format for included images. This format has to be easily modified. Overlay of figures and characters on top of the images to annotate findings. Provide for placing the report on a network as DICOM files or BMP or JPEG format. Provide a print function.

Comparison Table:

Feature	Aquarius Workstation	Imatron Ultra Access K972903	TeraRecon IiVS K994329
2D Image Review	Yes	Yes	Yes
Multiplanar reformatting	Yes	Yes	Yes
3D Volume Rendering	Yes	Yes	Yes
Maximum Intensity Projection	Yes	Yes	Yes
Image Archiving	Yes	Yes	Yes
Image Filming	Yes	Yes	Yes
Image Transfer or Network Connectivity	Yes	Yes	Yes
Examination of 2D image data from a calcium scan	Yes	Yes	Yes
Examination of calcium scan as a 3D volume	Yes	Yes	Yes
Semi-automated identification of regions that are considered calcium	Yes	Yes	No
User override of automatically identified regions	Yes	Yes	No
Automatic calculation of calcium score	Yes	Yes	No*
Ability to measure CT numbers on a 2D image	Yes	Yes	Yes
Identification of mistriggered slices	Yes	Yes	No
Saving of calcium data with patient exam data	Yes	Yes	No
Creation of a calcium report	Yes	Yes	No
Comparison of multiple scans	Yes	Yes	Yes
Identification of mistriggered data	Yes	Yes	No
Deselection of a mistriggered image	Yes	Yes	No
Creation of a parametric image	Yes	Yes	No
Indications for use – general medical imaging workstation	Yes	Yes	Yes
Indications for use – calcium	Yes	Yes	Yes**

* = manual calculation previously ** = calculated value previously

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

TeraRecon, Inc.
% Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
PLEASANT HILL CA 94523-3389

Re: K011142
Aquarius Workstation
Dated: April 11, 2001
Received: April 13, 2001
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) NUMBER: K01 1142

DEVICE NAME : AQUARIUS WORKSTATION

INDICATIONS FOR USE:

To acquire, store, transmit, and display medical images from medical scanning devices such as EBT, CT or MRI and patient reports of various types. Teleradiology, image acquisition, distribution, archiving, image manipulation, 3D and 4D visualization are supported. The software supports post-processing based or dynamic CT or MR images continuously acquired to aid in the assessment of time-dependant behavior of the image density or dimension of certain regions of interest. Calcium Scoring from whole body computed tomography derived measurements, for non-invasive detection and quantification of atherosclerotic plaque. Tools for histogram analysis of the density distribution of certain regions of interest are provided. A database management and report generation tool is included.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K011142

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional format 1-2-96)